DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 17, 2014

Gynetech, PTY. LTD.
% Kevin MacDonald
Regulatory Consultant
MacDonald Consulting
229 Marvilla Circle
Pacifica, CA 94044

Re: K142164
Trade/Device Name: ManipulatOR and ManipulatOR PRO
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKF
Dated: November 17, 2014
Received: November 19, 2014

Dear Kevin MacDonald,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142164

Device Name
Gynetech ManipulatOR PRO and ManipulatOR

Indications for Use *(Describe)*
The ManipulatOR is indicated for manipulation of the uterus during laparoscopic procedures including laparoscopic assisted vaginal hysterectomy (LAVH), laparoscopic tubal occlusion, and diagnostic laparoscopy. The ManipulatOR, when used together with the McCartney Tube, is indicated for manipulation of the uterus during laparoscopic procedures requiring maintenance of pneumoperitoneum, such as total laparoscopic hysterectomy (TLH).

The ManipulatOR PRO is indicated for manipulation of the uterus during laparoscopic procedures such as laparoscopic assisted vaginal hysterectomy (LAVH), total laparoscopic hysterectomy (TLH), laparoscopic tubal occlusion and diagnostic laparoscopy. The ManipulatOR PRO maintains pneumoperitoneum by sealing the vagina once colpotomy is performed.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21CFR § 807.92(c).

Submitted by:	Gynetech Pty Ltd Unit 7, 6-8 Macquarie Drive, Thomastown 3074, Australia Phone: +61 3 9413 5555 Contact email: qa@gynetech.com.au Fax: +61 3 9413 5555
Contact Person	Kevin MacDonald Clinical/Regulatory Consultant 229 Marvilla Circle Pacifica, CA 94044 Phone: 415-609-9875 Email: k-macdonald@sbcglobal.net
Date Prepared:	December 15, 2014
Proprietary Name:	ManipulatOR, ManipulatOR PRO
Common Name:	Uterine elevator; uterine manipulator
Classification:	LKF, Unclassified, Pre-Amendment Cannula, Manipulator/Injector, Uterine
Predicate Devices:	Primary Predicate Device: ConMed, VCare Vaginal-Cervical Ahluwalia's Retractor-Elevator, K071907
Device Description:	The ManipulatOR and ManipulatOR PRO are sterile, single-use uterine manipulators indicated for uterine manipulation and preventing loss of pneumoperitoneum during laparoscopic gynecology procedures. The ManipulatOR and ManipulatOR PRO are silicone insulated and anatomically designed stainless steel manipulators with a silicone intrauterine balloon at one end and an external handle at the other end. The balloon is inflated with air using a 20cc syringe that is supplied with the device. The ManipulatOR and ManipulatOR PRO are designed to improve physician visibility of the uterus and cervix during various medical examinations and procedures. Like many uterine elevators currently

	in the market place, the ManipulatOR and ManipulatOR PRO are designed for use in surgical procedures requiring cervical uterine motions with elevation and retraction of the vaginal fornices. The ManipulatOR and ManipulatOR PRO can help to create the tension on the tissue to assist in ligament dissection. In the most commonly used procedure, the total laparoscopic hysterectomy, the uterine elevator must expose the fornix and seal the vagina following removal of the uterus.
Indications for Use:	The ManipulatOR is indicated for manipulation of the uterus during laparoscopic procedures including laparoscopic assisted vaginal hysterectomy (LAVH), laparoscopic tubal occlusion, and diagnostic laparoscopy. The ManipulatOR, when used together with the McCartney Tube, is indicated for manipulation of the uterus during laparoscopic procedures requiring maintenance of pneumoperitoneum, such as total laparoscopic hysterectomy (TLH). The ManipulatOR PRO is indicated for manipulation of the uterus during laparoscopic procedures such as laparoscopic assisted vaginal hysterectomy (LAVH), total laparoscopic hysterectomy (TLH), laparoscopic tubal occlusion and diagnostic laparoscopy. The ManipulatOR PRO maintains pneumoperitoneum by sealing the vagina once colpotomy is performed.
Summary of Performance Data	The following product performance testing was successfully completed to confirm the subject device met the user requirements for the proposed intended use: • Air Leak Test – inflation of the balloon to confirm the system and balloon integrity would be maintained during “worst” case conditions. • Balloon destructive testing - Balloon integrity when exposed to maximum inflation volume. • Repeat inflation/deflation of balloon • Correlation of balloon inflated diameter and infused balloon volume • Tensile Testing of all critical bonds • Tensile Testing of entire system • Compatibility of ManipulatOR PRO with McCartney Tube • Force required for tip deflection • Locking forces of clamp on ManipulatOR PRO • Ease of movement of ManipulatOR PRO when clamp is unlocked. • Accelerated age testing • Packaging validation testing • Sterility Validation testing

Summary of Safety Data/Biocompatibility Testing	Per ISO 10993-1, the following biocompatibility tests were conducted and confirmed all direct body materials used in the subject device are biocompatible for the proposed intended use: • MEM Elution Cytoxicity • Mucosal (vaginal) Irritation • Guinea Pig Maximization Sensitization
Substantial Equivalence Discussion:	The subject and predicate devices do not have the same indication statement but have the same intended use (manipulations of the uterus during laparoscopic procedures). The differences do not raise any concerns, because the subject devices have narrowed indications compared to the predicate device. The ManipulatOR PRO and predicate device have the same fundamental technological characteristics, including the following: ▪ A rigid, anatomically curved manipulator shaft ▪ A balloon at distal end of the shaft ▪ A valve and handle at proximal end of the shaft ▪ A cervical cup ▪ A vaginal cup ▪ A clamp to secure the vaginal cup ▪ The vaginal cup seals the vaginal cavity from within to maintain pneumoperitoneum and prevent abdominal deflation. • The ManipulatOR and predicate device have the following same fundamental technological characteristics: ▪ A rigid, anatomically curved manipulator shaft ▪ A balloon at distal end of the shaft ▪ A valve and handle at proximal end of the shaft The ManipulatOR does not have the cervical cup and vaginal cup compared to the predicate device. However, the differences do not raise safety and effectiveness concerns, because ManipulatOR may be used with the access tube if maintenance of pneumoperitoneum is needed. • The subject devices are different from the predicate device in that they are not designed for injection of fluids or gases into the uterus. The difference does not raise safety and effectiveness concerns, because the subject devices are not indicated for injection of fluids or gases into the uterus.

	The subject and predicate devices use different materials in the balloon and other patient contact components. The different materials raise concerns on biocompatibility and mechanical performance of the subject devices. However, these concerns do not represent new types of safety and effectiveness questions. Accepted scientific methods exist for assessment of the difference (e.g., biocompatibility testing for safety and bench testing for mechanical performance). The biocompatibility and bench testing demonstrated that the subject devices are safe and effective.
Conclusion:	The ManipulatOR and ManipulatOR PRO share most technological and design features and functions with the predicate device. The performance testing show the safety and functionality of the Gynetech devices. In summary, the Gynetech ManipulatOR and ManipulatOR PRO are substantially equivalent to the predicate devices, ConMed VCare Vaginal-Cervical Ahluwalia's Retractor-Elevator.